510(k) Summary

FEB 2 8 2014

Proprietary Name:	Fixos Screw System
Common Name:	Bone Screws
Classification Name and Reference:	Smooth or threaded metallic bone fixation fastener 21 CFR §888.3040
Regulatory Class:	Class II
Product Codes:	87 HWC : Screw, Fixation, Bone
Sponsor:	Stryker Trauma AG Bohnackerweg 1 CH-2545 Selzach Switzerland
Contact Person:	Estela Celi Regulatory Affairs Specialist 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6461 Fax: (201) 831-3461 estela.celi@stryker.com
Date Prepared:	November 7, 2013

Description

This Traditional 510(k) submission is being supplied to the U.S. FDA to provide authorization to market the new Fixos Screw System. The Fixos Screw System is an internal fixation device that consists of various types of screws to treat a number of different types of fractures in small and long bones. The subject components will be available sterile and non-sterile.

Intended Use

The Stryker Fixos Screw System is a single use device intended for the fixation, correction or stabilization of small and long bones in adult and adolescent patients.

Indications

The Stryker Fixos Screw System is a single use device intended for the fixation, correction or stabilization of small and long bones in adult and adolescent patients. Indications include:

Ø4.0mm Headless Screw:

- Fractures of the tarsals and metatarsals
- Fractures of the olecranon, distal humerus
- Fractures of the radius and ulna
- Patella fractures
- Distal tibia and pilon fractures
- Fractures of the fibula, medial malleolus, os calcis
- Tarso-metatarsal and metatarsophalangeal arthrodesis
- Metatarsal and phalangeal osteotomies
- Osteochondritis dissecans
- Fractures of the pelvic ring
- Small cancellous fragments of the small and long bones

Ø5.0mm Headless Screw:

- Medial and lateral malleolar and pilon fractures
- Proximal and distal humerus fractures
- Fractures of the olecranon process
- Tibial plateau fractures
- Os calcis, talar and patellar fractures
- Fractures of the pelvis and acetabulum
- Arthrodesis of the tarsals

Ø7.0mm Headless Screw:

- Tibial plateau fractures
- Ankle arthrodesis
- Calcaneus osteotomies

Summary of Technologies

Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the following predicate devices:

- Asnis III Cannulated Screw System-K000080
- Darco Headless Compression Screw-K080850
- Synthes 4.5mm and 6.5mm Headless Compression Screws-K080943

Non-Clinical Testing
Non-clinical laboratory testing was performed on the Fixos Screw System components to determine substantial equivalence. Testing demonstrated that Fixos Screw System is substantially equivalent to the predicate device currently cleared for marketing.

The following testing was performed

- Insertion Torque Testing
- Shear-off Testing
- Pull-out Testing

Clinical Testing
Clinical testing was not required for this submission.

Conclusion
The Fixos Screw System is substantially equivalent to the predicate device identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 28, 2014

Stryker Trauma AG
Ms. Estela Celi
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K133451
Trade/Device Name: Fixos Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: January 28, 2014
Received: January 29, 2014

Dear Ms. Celi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133451

Device Name: Fixos Screw System

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth D Frank -S

Division of Orthopedic Devices